THE CLAIMS

What is claimed is:

1. A propellant free buccal spray composition for transmucosal administration of sumatriptan a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and

a polar solvent in an amount between 30 and 99 percent by weight of the total composition.

2. The composition of claim 1, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

3. The composition of claim 2, wherein the polar solvent is present in an amount between 37 and 98 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

4. The composition of claim 3, wherein the polar solvent is present in an amount between 60 and 97 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

5. The composition of claim 1, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration.

6. The composition of claim 1, wherein the polar solvent comprises polyethylene glycol.

7. The composition of claim 1, wherein the polar solvent comprises ethanol.

8. The composition of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

9. The composition of claim 1, comprising sumatriptan succinate.

10. A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 1.

11. The method of claim 9, wherein the amount of the spray is predetermined.

12. A buccal spray composition for transmucosal administration of sumatriptan or a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount of between 0.1 and 25 percent by weight of the total composition;

a polar solvent in an amount between 10 and 97 percent by weight of the total composition; and

a propellant in an amount between 2 and 10 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or branched configuration.

13. The composition of claim 12, further comprising a taste mask and/or flavoring agent in an amount between 0.05 and 10 percent by weight of the total composition.

14. The composition of claim 13, wherein the polar solvent is present in an amount between 20 and 97 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.1 and 15 percent by weight of the total composition, the propellant is present in an amount between 2 and 5 percent by weight of the composition, and the taste mask and/or flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.

15. The composition of claim 14, wherein the polar solvent is present in an amount between 25 and 97 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.2 and 25 percent by weight of the total composition, the propellant is present in an amount between 2 and 4 percent by weight of the composition, and taste mask and/or flavoring agent is present in an amount between 0.1 and 2.5 percent by weight of the total composition.

16. The composition of claim 12, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration.

17. The composition of claim 16, wherein the polar solvent comprises polyethylene glycol.

18. The composition of claim 16, wherein the polar solvent comprises ethanol.

19. The composition of claim 13, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

20. The composition of claim 12, wherein the propellant is selected from the group consisting of propane, *N*-butane, *iso*-butane, *N*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

21. The composition of claim 12, comprising sumatriptan succinate.

22. A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 12.

23. The method of claim 22, wherein the amount of the spray is predetermined.

24. A propellant free buccal spray composition for transmucosal administration of sumatriptan or a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount between 0.005 and 55 percent by weight of the total composition; and

a non-polar solvent in an amount between 30 and 99 percent by weight of the total composition.

25. The composition of claim 24, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

26. The composition of claim 25, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

27. The composition of claim 24, wherein the solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

28. The composition of claim 27, wherein the solvent is a triglyceride.

29. The composition of claim 24, comprising sumatriptan succinate.

30. A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 24.

31. The method of claim 30, wherein the amount of the spray is predetermined.

32. A buccal spray composition for transmucosal administration of sumatriptan or a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount between 0.05 and 50 percent by weight of the total composition; and

a non-polar solvent in an amount between 19 and 85 percent by weight of the total composition; and

a propellant in an amount between 5 and 80 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or brancehed configuration.

33. The composition of claim 32, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

34. The composition of claim 33, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

35. A buccal spray composition for transmucosal administration of sumatriptan or a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount between 0.01 and 40 percent by weight of the total composition;

a non-polar solvent in an amount between 25 and 89 percent by weight of the total composition;

a propellant in an amount between 10 and 70 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or branched configuration; and

a taste mask and/or flavoring agent is present in an amount between 1 and 8 percent by weight of the total composition.

36. The composition of claim 35, wherein the propellant is present in an amount between 20 and 70 percent by weight of the total composition, the non-polar solvent is present in an amount between 25 and 75 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount from

between 0.25 and 35 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 2 and 7.5 percent by weight of the total composition.

37. The composition of claim 32, wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, *n*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

38. The composition of claim 37, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

39. The composition of claim 32, wherein the solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

40. The composition of claim 39, wherein the solvent is a triglyceride.

41. The composition of claim 32, comprising sumatriptan succinate.

42. A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 32.

43. The method of claim 42, wherein the amount of the spray is predetermined.

44. A buccal spray composition for transmucosal administration of sumatriptan or a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount between 0.2 and 10 percent by weight of the total composition; and

a polar solvent comprising propylene glycol and ethanol in an amount between 50 and 99 percent by weight of the total composition.

45. A propellant free buccal spray composition for transmucosal administration of sumatriptan or a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and

a mixture of a polar solvent and a non-polar solvent in an amount of between 30 and 99.69 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1.

46. The composition of claim 45, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

47. The composition of claim 46, wherein the polar solvent is present in an amount between 37 and 98 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

48. The composition of claim 47, wherein the polar solvent is present in an amount between 60 and 97 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

49. The composition of claim 45, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

50. The composition of claim 46, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

51. The composition of claim 45, comprising sumatriptan succinate.

52. A method of administering sumatriptan or a pharmaceutically acceptabl;e salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 45.

53. The method of claim 52, wherein the amount of the spray is predetermined.

54. A buccal spray composition for transmucosal administration of sumatriptan or a pharmaceutically acceptable salt thereof comprising:

sumatriptan or a pharmaceutically acceptable salt thereof in an amount between 0.05 and 50 percent by weight of the total composition;

a mixture of a polar solvent and a non-polar solvent in an amount between 10 and 97 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1; and

a propellant in an amount between 5 and 80 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or branched configuration.

55. The composition of claim 54, further comprising a taste mask and/or flavoring agent is present in an amount between 0.01 and 10 percent by weight of the total composition.

56. The composition of claim 55, wherein the propellant is present in an amount between 10 and 70 percent by weight of the total composition, the solvent is present in an amount between 20 and 97 percent by weight of the total composition, the sumatriptan or a pharmaceutically acceptable salt thereof is present in an amount from between 0.1 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 1 and 8 percent by weight of the total composition.

57. The composition of claim 54, wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, *n*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

58. The composition of claim 57, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

59. The composition of claim 54, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

60. The composition of claim 54, comprising sumatriptan succinate.

61. A method of administering sumatriptan or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 54.

62. The method of claim 61, wherein the amount of the spray is predetermined.

63. A method of treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

64. A method of treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 12.

65. A method of treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 24.

66. A method of treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 32.

67. A method of treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 45.

68. A method of treating migraines in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 54.